

VII. 510(k) Summary

A. Sponsor/Submitter: Marine Polymer Technologies, Inc.
107 Water Street
Danvers, MA 01923
Phone: 781-270-3200
Fax: 781-270-1133

B. Contact Person Sergio Finkielstein President JUL 28 2010
781-270-3200 x 13

C. Date of Submission: July 13, 2010

D. Trade (Brand) Name: Talymed™

E. Common Name: Dressing, wound hydrophylic

F. Classification Name/Number: Unclassified

H. Product Code: FRO

I. Predicate Devices: Marine Polymer Technologies, Taliderm K070557
Cook Biotech Int. Oasis Wound Matrix K061711

J. Intended Use:
Talymed™ is indicated for the management of wounds including:
Diabetic ulcers
Venous ulcers
Pressure wounds
Ulcers caused by mixed vascular etiologies
Full thickness and partial thickness wounds
Second degree burns
Surgical wounds-donor sites/grafts, post-mohr's surgery,
post-laser surgery, and other bleeding surface wounds,
Abrasions, lacerations
Traumatic wounds healing by secondary intention
Chronic vascular ulcers
Dehisced surgical wounds.

K. Device Description:

Talymed™ is a sterile wound matrix comprised of shortened fibers of poly-N-acetylglucosamine, isolated from microalgae.

L. Summary of Substantial Equivalence:

Marine Polymer Technologies has submitted information on indication for use, biocompatibility and performance characteristics to establish that Talymed™ is substantially equivalent to currently marketed predicate device. Talymed™ has essentially the same intended use as the predicate devices. Results of scientific testing have ensured that all materials are biocompatible, no new adverse effects were introduced and physical properties are appropriate for the intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Marine Polymer Technologies
% Mr. Sergio Finkielstein
President
107 Water Street
Danvers, Massachusetts 01923

JUL 28 2010

Re: K102002

Trade/Device Name: Talymed™
Regulatory Class: Unclassified
Product Code: FRO
Dated: July 13, 2010
Received: July 15, 2010

Dear Mr. Finkielstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

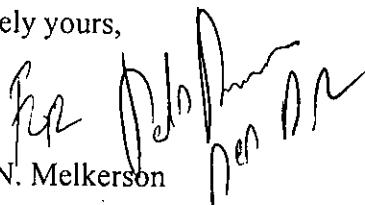
Page 2 - Mr. Sergio Finkelsztein

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director

Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number

K 102002

Device Name: TalyMed™

JUL 28 2010

Indications for use:

TalyMed™ is indicated for the management of wounds including:

- Diabetic ulcers
- Venous ulcers
- Pressure wounds
- Ulcers caused by mixed vascular etiologies
- Full thickness and partial thickness wounds
- Second degree burns
- Surgical wounds-donor sites/grafts, post-mohr's surgery, post-laser surgery, and other bleeding surface wounds,
- Abrasions, lacerations
- Traumatic wounds healing by secondary intention
- Chronic vascular ulcers
- Dehisced surgical wounds.

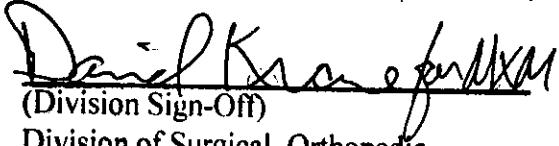
Prescription Use
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102002